

DETAILED ACTION

1. Claims 1-8, 11-13 and 15-19 are now pending in the instant application.

Information Disclosure Statement

2. Applicants' Information Disclosure Statement (IDS), submitted February 11, 2008, has been considered by the Examiner. Please refer to the signed copy of Applicants' PTO-1449 form, submitted herewith.

Response to Amendment

3. Applicants' Amendment of February 11, 2008 has been reviewed by the Examiner and entered of record in the file. Accordingly, claims 1, 11 and 15 have been amended and claim 20 has been cancelled.
4. In the previous Office Action, Groups II-LVI, i.e. claims 1-8, 11-13 and 15-20 wherein A is other than phenyl, or CR3R4 do form a ring, or R5 does contain a Het ring, were withdrawn from further consideration as being drawn to nonelected inventions. The Examiner notes with appreciation the deletion of the nonelected subject matter from the claims.

Claim Rejections - 35 USC § 112

5. Claims 11, 15 and 20 previously rejected under 35 U.S.C. 112, first paragraph, as not being fully enabled. Claim 20 has been cancelled, and Applicants have amended claim 11 in order to incorporate a particular list of inflammatory diseases, therefore the enablement rejections of claims 11 and 20 are withdrawn. Applicants have amended claim 15 such that the claim is directed to a method of treating cancer, which is not enabled. However, treating certain specific types of cancer are enabled, please refer to the Examiner's Amendment below.

Art Unit: 1626

Double Patenting

6. Claims 1-8, 11-13 and 15-20 previously provisionally rejected on the ground of nonstatutory double patenting over claims 1-11, 21, 26 and 33 of copending Application No. 09/868,884. In view of Applicants' persuasive arguments, the double patenting rejections are withdrawn.

EXAMINER'S AMENDMENT

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Teresa A. Lavoie, and correspondence via electronic mail on April 23, 2008.

The application has been amended as follows:

Claim 15, line 2, after the word "cancer" please insert the following:

", wherein the cancer is selected from the group consisting of colorectal cancer, breast cancer, gastric cancer, Hodgkin's lymphoma, head and neck squamous cell carcinoma, Chronic Myelogenous Leukemia, and Acute Lymphoblastic Leukemia," .

REASONS FOR ALLOWANCE

8. In view of Applicant's amendatory changes and cancellations, claims 1-8, 11-13 and 15-19 are allowable over the prior art, as newly renumbered claims 1-16. The following is an examiner's statement of reasons for allowance:

Art Unit: 1626

This invention relates to novel thiophene-carboxamide derivatives, their pharmaceutical compositions, and their methods of use. The allowable compounds are limited to compounds according to formula (I) of claim 1. Certain thiophene-carboxamide compounds are known in the art, however the aspect of preparing the instant claimed phenyl-thiophene-carboxamide derivatives, with NF- κ B inhibitory activity as IKK inhibitors, is novel and unobvious. The instant compounds were tested for selective inhibition of IKK-1 and IKK-2 (please refer to inhibitory results, IC₅₀ values, etc. found in pages 45-48 of the specification). The instant compounds' inhibitory effect on TNF α was also measured, which in turn inhibits NF- κ B activation and makes them useful as anti-inflammatory agents for treating inflammatory diseases such as asthma, rheumatoid arthritis, COPD, etc. Please also refer to the Karen, M. et al, Luo, et al., and Orłowski et al journal articles, which discuss the role of NF- κ B in certain specific types of cancer, and that IKK-driven inhibition of NF- κ B can result in tumor regression for treating certain forms of cancer (i.e. colorectal cancer, breast cancer, gastric cancer, Hodgkin's lymphoma, head and neck squamous cell carcinoma, Chronic Myelogenous Leukemia, and Acute Lymphoblastic Leukemia).

After a thorough search, the closest relevant art, U.S. Pat. No. 7,358,376 to Baxter et al. was found to teach similar thiophene carboxamide derivatives as anti-inflammatories. However the '376 patent fails to teach or render obvious the same instant claimed compounds according to formula (I), and does not fairly suggest the same methods of preparation or use.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for

Allowance.”

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins
April 28, 2008

/Joseph K. McKane/
SPE, Art Unit 1626